



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1574]

Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices); Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices).” FDA is issuing this draft guidance to update the policy regarding the use of animal-derived material in medical device manufacturing. These animal-derived materials may carry a risk of transmitting infectious disease when improperly collected, stored, or manufactured. The guidance describes the information you should document at the manufacturing facility and include in any premarket submissions. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices)” to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Scott McNamee, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3416, Silver Spring, MD 20993-0002, 301-796-5523; or Charles Durfor, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G424, Silver Spring, MD 20993-0002, 301-796-6970.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance entitled “Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices)” is intended to update the 1998 guidance of the same name regarding the use of animal-derived material in medical device manufacturing. The 1998 guidance addressed ways to reduce the potential for exposure to

bovine spongiform encephalopathy. The draft guidance continues to focus on the control of transmissible disease, and contains recommendations for documenting the source of animal tissue, conducting viral inactivation validation studies, as well as recommendations about the role of careful animal husbandry in ensuring safe tissue sources.

The information in this guidance is applicable to all medical devices that contain or are exposed to animal-derived materials (e.g., bovine, ovine, porcine, avian materials) with the exception of in vitro diagnostic devices. The guidance describes the information you should document at the manufacturing facility and include in any premarket submissions. Consideration of these issues should aid in reducing the risk of infectious disease transmission by medical devices.

This draft guidance, when finalized, will supersede the guidance entitled “Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)”, announced in the Federal Register of November 6, 1998 (63 FR 60009).

II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on medical devices containing materials derived from animal sources (except for in vitro diagnostic devices). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive “Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)” you may either send an email request to ds mica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 2206 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 814 subpart H have been approved under OMB control number 0910-0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be

seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: January 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-01232 Filed 01/22/2014 at 8:45 am; Publication Date: 01/23/2014]